REMARKS

Claims 1-16 are pending. If the current amendments do not place the case in condition for allowance, entry thereof for purposes of appeal is respectfully requested because issues on appeal will be reduced.

Support for Amendments

Support for the phrase "in the form of an orifice through which an electric current is flowing", added to claim 1 line 4, can be found in the specification as filed on page 13, line 7. Support for other amendments are found at various places in the original specification as filed. The amended claims more clearly define the invention.

Claim Objections

In view of the current amendments to claims 15 and 16, all objections in paragraph 1 on page 2 of the last Office Action, are believed to have been overcome.

Claims 1 and 14 are not obvious

The rejection of claims 1 and 14 in paragraph 3 of the last office action as obvious under 35 USC 103 over USP 4,021,117 (Göhde '117), in view of USP 4,447,883 (Farrell '883) is traversed on multiple grounds. As explained more fully below it would not be obvious to combine these two references in the

manner suggested by the examiner. Even if it were obvious to the skilled artisan to combine these two references, the result would still not be the subject matter claimed.

Non-Obviousness Over Göhde in View of Farrell

In paragraph 3 of the last Office Action, the Examiner rejected claims 1-4, 8-10 and 14 as being obvious over Göhde '117, in view of Farrell '883.

The Examiner admits that Göhde '117 does not disclose:

> . . . a method of processing the raw data by using a true average flight time and a true average wait time to obtain a corrected count of particles. (last Office Action; page 3, line 6)

While this statement is true, it does not tell the entire story. In fact, Göhde '117 discloses neither "true average flight time" nor "true average wait time".

It is notoriously well known to attempt to count small particles in a liquid sample employing the Coulter effect. To take advantage of this effect, a large number of prior art devices employ logic circuits to manipulate the raw data which is in the form of voltage pulses. When two particles follow each other closely through the aperture, it is not always possible to distinguish between the two pulses. This can result in what has been termed a "coincidence error". Such a coincidence error results in a machine determined number of particles which is less than the actual number of particles. Some particles are "lost". The problem is sometimes referred to as a "coincidence loss". Such coincidence

losses are explained in the application as filed in general and are graphically illustrated in Figure 2a of the application as filed. The attention of the Examiner is respectfully invited to the last two pulses of the four pulses shown in Figure 2a. There is a long-felt need in the art to correct for coincidence loss or to otherwise accurately determine the actual number of particles present in a sample.

Göhde '117 attempts to solve the coincidence loss problem in a manner completely different than that of the present invention. Göhde '117 does this by "measuring the maximum amplitude of each of the [voltage] signals" (Göhde '117 at column 8, line 4). Then Göhde '117 proceeds with "measuring the area under each of the [voltage] signals" (Göhde '117 at column 8, line 6). Thereafter, in order to further handle coincidence loss Göhde '117 then proceeds with "determining the ratio of the measurements of maximum amplitude to area" (Göhde '117 at column 8, line 8).

More specifically, Göhde '117 merely discloses an alternative method for correcting particle counts. Göhde '117 discloses correcting for coincidence loss by detecting and counting when a coincidence event has occurred and adding all of these to the raw count. Such a method can handle conventional count rates of 4,000 cells per second, which corresponds to a particle concentration of about 50,000 cells/μL. The method of Göhde '117 is not accurate at high

concentrations of 450,000 cells/µL, as is handled by the present invention. At 450,000 cells/µL the expected count rate is 64,000 counts per second and the actual raw count is 16,000. Therefore, at high concentrations there are on average 4 coincident cells per actual single raw count and adding back one coincident count per raw count would be inaccurate. The amount of coincidence loss increases non-linearly as the concentration increases. For these reasons Göhde '117 method would not be able to handle the high concentrations of the present invention.

The Office Action relies on Farrell '883 for teaching a method of processing raw data by using a true average flight time and a true average wait time to obtain a corrected count of particles

There is absolutely no motivation in either Göhde '117 or in Farrell '883 that would motivate the skilled artisan to combine their teachings. Göhde '117 discloses and claims the use of his "area-under-the-curve" method of reducing coincidence loss. Göhde '117 makes no suggestion what so ever of handling coincidence loss by any means other than the disclosed means. The deficiencies in Göhde '117 are not supplied by Farrell '883.

The object of Farrell '883 is to improve the counting of a small type of cell, i.e. Platelets, in the presence of a large type of cell, i.e. Red blood cells. It corrects the coincidence loss of platelets due to larger red cells. This is a mixed mode type

of count correction where two types of cells are being counted at the same time. The present invention, on the other hand, deals with count correction of a single type of cells a certain size or larger, i.e. Red blood cells or White blood cells. Thus, the methods of Farrell '883 and the present invention have different objectives and are not comparable.

Farrell '883 does not disclose a "true average flight time" as that term is employed in pending claim 1. Neither does Farrell '883 disclose "a true average wait time" as that term is also employed in pending claim 1. In particular, DWT/IT is not an average flight time per cell as stated in the Office Action.

Farrell '883 discloses a standard wait time formula with only a new multiplier (1 + ((R * Pm)/IT)), where Pm is the average Flight Time for a single Platelet cell. Pm is not an average Flight Time for Reds and Platelets. R is the wait time corrected for red cell count. Thus, the term R * Pm is the red cell count times the average Platelet Flight Time. Dividing by IT gives a fraction which when added to 1 will increase the Platelet count.

The object of Farrell '883 is to reduce the coincidence loss of platelets due to Red cells. The wait time formula disclosed includes the term DWT/IT.

In the wait time method the sample is counted for a period of time called IT (column 3, lines 45-46). During this time there are two states. Particles are in the sensing zone and above a threshold, or they are not. The sum of these two

times is the total time. DWT represents the time above the threshold (column 3, lines 43-45). If TWT represents the time below the threshold count, then IT = DWT + TWT. Thus DWT/IT does not represent the average flight time per cell.

The wait time method of Farrell '883 assumes that the average pulse high time can be ignored as it is small compared to the average low time. This is sufficient at low concentrations. However, at high concentrations and with variation in the size of the particles the average true flight time must be considered. Based on the method in Farrell '883, the flight time would be too corrupted at high concentrations to be of any value. Thus, for these reasons, Farrell '883 does not make up for the deficiency in Göhde '117.

Furthermore, assuming without deciding, as the Examiner argues, that a portion of the formula shown in Farrell '883 at column 4, lines 10-18 is equal to "wait time", the wait time of Farrell '883 is raw wait time, not true average wait time. Farrell '883 represents a different approach to the solution of the problem solved here. Farrell '883 is cited and distinguished in the application as filed.

> . . . This [Farrell] method calculates the average time between particles or total wait time of the counted particle stream and sets the corrected count equal to the inverse of the average wait time. 'The basic theoretical formula is that the frequency or counts per second is equal to the inverse of the average period of the particle pulse stream. (Specification as filed, page 3, lines 5-8)

The above-described method of Farrell '883 is not the claimed method. The

specification goes on to point out the deficiencies in Farrell and states:

> This [Farrell] method assumes that the effects of the aperture size, particle size and flight time can be ignored. This method operates based on the wait time containing information about lost counts due to coincidence. If two particles go through the aperture too close together, then one count is lost. However, the two particles take up to twice as long to go through the aperture. This reduces the Total Wait Time and causes the true count to be increased. (Specification as filed, page 3, lines 9-14)

The Farrell method is not and cannot be the method here claimed. The specification as filed concludes by stating:

> Therefore the [Farrell '883] average flight time cannot be accurately determined from the [Farrell '883] Total Flight Time divided by the [Farrell '883] raw count."

There is no motivation in either Farrell '883 or Göhde '117 for combining their teachings. There is no reason to employ the various times of Farrell '883 in the disclosure of Göhde '117 because Göhde '117 is not concerned with flight times, but rather is concerned with the area under a curve. However, even assuming, *arguendo*, the obviousness of the combination, the result would still not be a subject matter within the scope of that claimed since Farrell '883 does not disclose "a true average flight time" nor does Farrell '883 disclose "a true average wait time" as those terms are employed in the instant case in the relevant claims.

Claims 2, 3, 4, 8, 9, and 10 are patentable

The rejection of claims 2, 3, 4, 8, 9, and 10 is traversed, but need not be dealt with separately. Each of these claims is dependent on claim 1. Since claim 1 is patentable for the above reasons, these claims are all also patentable.

Claims 5-7 are patentable

The rejection of claims 5-7 is traversed, but need not be dealt with separately. Each of these claims is dependent on claim 1 either directly or indirectly. Since claim 1 is patentable for the above reasons, these claims are all also patentable.

Non-Obviousness over Graham '242 in View of Farrell '883

The rejection of Claim 11 over USP 6,259,242 (Graham '242) in view of Farrell '883 is traversed. Farrell '883 does not teach what is here claimed as explained above. Combining the teachings of Farrell '883 with any other reference simply does not meet the terms of the claims. There is furthermore no motivation for combining the teachings of these two references.

Non-Obviousness over Gear '129 in View of Jones '237

The rejection of claims 12 and 13 over USP 4,090,129 (Gear '129) in view of USP 5,452,237 (Jones '237) is respectfully traversed.

Gear '129 is not concerned with correcting raw pulse counts.

The coincidence error correction system of Jones '237 is not concerned with "true average wait time" or with "true average flight time" as those terms are employed in the pending claims.

It would not be obvious to combine the teachings of Jones '237 with those of Gear '129 since Gear '129 is not desirous of any count correction. Even if the teachings of Gear '129 and Jones '237 were combined, the result would still not be subject matter within the scope of claim 11.

Claim 15 is Novel

The rejection of claim 15 over Farrell '883 under 35 USC 102(b) in paragraph 9 on page 12 of the last office action is traversed but has been rendered moot by the present amendments to this claim. The current amendments to the claim make clear the definitions of terms employed herein. This makes it clear that these terms are used in the present claims in a manner wholly different from that structure shown in Farrell '883.

Claim 16 is not obvious

The rejection of Claim 16 in paragraph 10 on page 13 of the last office action as obvious under 35 USC 103 over Farrell '883 in view of USP 5,247,461 (Berg '461) is traversed.

The Examiner candidly admits, on page 14 at line 16, that Farrell '883 does not disclose element K of Claim 16 which reads as follows:

> K. a coincidence-corrected count generator which receives the average period count from the average period count generator and which also receives an empirically determined correction factor; and then applies the empirically determined correction factor to the average period count, thereby determining the true count of the number of particles in the sample.

The Examiner argues that this subject matter missing from Farrell '883 is supplied by Berg '416 pointing to element number 28 in Figure 4 of Berg '416. Element 28 is not a count generator but rather is the graphic representation of a process step of "apply[ing] coincidence corrections to data array". Berg '416 receives data from step 4 not from the structural elements recited in paragraph K of claim 16. Berg '416 does not disclose the subject matter of pending claim 16.

In further support of the rejection the Examiner relies on a portion of claim 1 of Berg '416. The portion relied on reads as follows:

> What is claimed:
>
> 1. A method of measuring particle distribution within a suspension of particles in liquid, comprising the steps of passing the suspension through the sensing zone of apparatus for sensing discrete particles, deriving from said sensing apparatus a plurality of values corresponding to a first approximation of the number of particles in each of a plurality of different sizes, calculating a coincidence correction factor for each of said values, and correcting each of said values individually by applying its respective coincidence factor, said coincidence correction factor being derived from said first approximation data for a range of said values to compensate for the fact that a number of particles represented by each of a plurality of such values is partially due to coincidence of

> multiple particles having smaller sizes which are . . . (Berg '416; Column 13, line 43 through column 14, line 12)

Claims define the scope of the limited monopoly. Claims are directed to Examiners, Patent Attorneys and sometimes judges. Nothing in the above quoted claim teaches one skilled in the art how to construct element K of claim 16, nor how to motivate the skilled artisan to substitute this alleged structure for any structure of Farrell '883.

Summary

In summary, it is respectfully submitted that all grounds of rejection have been overcome by argument or amendment and that the Examiner would be justified in passing the case to issue. Such action is earnestly solicited.

The Examiner is respectfully requested to enter this Reply After Final in that it raises no new issues. Alternatively, the Examiner is respectfully requested to enter this Reply After Final in that it places the application in better form for Appeal.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of $920.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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